REMARKS

This Amendment is being submitted in response to the Office Action mailed on February 5, 2008, in connection with the above-identified application.

Reconsideration of the above-identified application in view of the following remarks is respectfully requested.

STATUS OF ACTION

Claims 1-8 are currently pending in the present application and under consideration. Applicant would like to thank the Examiner for the removal of the previously made rejections cited by the Office. Applicant respectfully requests reconsideration of the currently pending claims in view of the below provided remarks.

REJECTION UNDER 35 U.S.C. SECTION 103

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips WO 01/51050 (hereinafter "Phillips"). Applicant respectfully traverses this rejection.

The Office suggests that Phillips discloses a liquid oral pharmaceutical composition for the suppression of gastric acid secretion, prepared by mixing omeprazole or another proton pump inhibitor or derivative thereof with a solution including at least one buffering agent. Lansoprazole is disclosed and multiple buffering agents, such as, sodium bicarbonate, are disclosed. Moreover, the Office states that Phillips further discloses the pharmaceutical composition comprising the PPI and at least one buffering agent in a form convenient for storage, whereby when the composition is placed into an aqueous solution, the composition

dissolves yielding a suspension suitable for enteral administration to a subject. (See, page 3 of Office Action). As admitted by the Examiner, Phillips fails to disclose or discuss the viscosity of the composition, but the Examiner suggests that it would be obvious to a person of ordinary skill the art to modify the viscosity in order to stabilize the solution and prevent settling of the PPI in the suspension as taught by Phillips in order to prepare an oral suspension for use as a suppressant of gastric acid secretion. (See, pages 3-4 of the Office Action). Applicant respectfully disagrees with the Examiner's conclusion and requests reconsideration.

Applicant believes that although the Phillips reference suggests a pharmaceutical composition that may be prepared by mixing a proton pump inhibitor (PPI) with a solution including at least one buffering agent, Phillips fails to suggests that the liquid vehicle or solution including the buffering agent has the specific pH parameters, or a viscosity as set forth by the presently claimed invention. The presently claimed invention specifically provides that the liquid vehicle has "a pH greater than 6.5 and a viscosity sufficient to maintain a uniform suspension of the PPI."

Although the Phillips reference discusses the benefits of using sodium bicarbonate and the desire of mixing the PPI with a solution including sodium bicarbonate, there is no suggestion that a liquid vehicle including the buffering agent has a pH of 6.5 or greater in order to obtain the desirable effect. Instead, one of the primary focuses of the Philips reference is to avoid the critical disadvantages associated with administering large amounts of sodium bicarbonate.

> In order to avoid the critical disadvantages associated with administering large amounts of bicarbonate, the PPI solution of the present invention is administered in a single dose which does not require any further administration of bicarbonate, or large amounts of bicarbonate, or other buffer following the administration of the PPI solution, nor does it require a large amount of bicarbonate or buffer in total. This is, unlike the prior art PPI solutions and

> administration protocols outlined above, the formulation of the present invention is given in a single does which does not require the administration of bicarbonate either before or after administration of PPI. The present invention eliminates the need to pre-or post-dose with additional volumes of water and sodium bicarbonate.. The amount of bicarbonate administered via the single dose administration of the present invention is less than the amount of bicarbonate administered as taught in the prior art references cited above.

(Phillips, page 29, lines 2-20)

This extensive discussion regarding sodium bicarbonate fails to suggest that the amount of sodium bicarbonate or buffering agent within Phillips provides a liquid vehicle or solution having a pH of 6.5 or greater. Moreover, Phillips suggests that the "buffering agent" "functions to substantially prevent or inhibit the acid degradation of the PPI by gastric acid sufficient to preserve the bioavailability of the PPI administered. The buffering agent is administered in an amount sufficient to substantially achieve the above functionality. Therefore, the buffering agent of the present invention, when in the presence of gastric acid, must only elevate the pH of the stomach sufficiently to achieve adequate bioavailability of the drug to effect therapeutic action." (Phillips, page 30, lines 19-28). As can be seen, there is no suggestion or discussion by Phillips that the solution can used in combination with the PPI having a pH of 6.5 or greater. One of ordinary skill in the art would not assume that a non-basic pH of 6.5 would achieve the desired effects of elevating the pH of the stomach as required by the Phillips reference. Accordingly, the Phillips reference does not make obvious the present claimed invention wherein the liquid vehicle has a pH of 6.5 or greater.

In addition, although Phillips references a "suspension" there is no suggestion of a particular viscosity that is desirable or would be necessary to be used in the invention as described by the Phillips reference. The Phillips reference provides that "the composition

dissolves yielding a suspension suitable for enteral administration to a subject The pharmaceutical composition is in a solid form prior to dissolution or suspension in an aqueous solution." (Phillips, page 33, lines 22-26). As can be seen, there is no suggestion by Phillips that a "uniform suspension" of the PPI is desirable or would be achieved by a certain viscosity as claimed by the present invention. Although one of ordinary skill in the art may recognize that Phillips suggests that a suspension may be created, one would not assume that this would require a "uniform suspension" as required by the present claims. Phillips merely suggest that a "suspension" is created. Accordingly, there would be no motivation to modify Phillips to obtain a viscosity to obtain a uniform suspension. More specifically, there is no suggestion or motivation to modify Phillips wherein the liquid has a viscosity sufficient to maintain a uniform suspension of the PPI for 15 minutes as provided for in claim 8 of the currently pending application.

In view of the above provided remarks, Applicant believes that the Office's current rejection has been overcome and has now been rendered moot. Applicant respectfully requests reconsideration and removal of the current rejections.

CONCLUSION

Reconsideration and withdrawal of rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

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